REMARKS

Claims 20-31 are pending in the application and have been examined. Claims 20-31 stand rejected. Reconsideration and allowance of Claims 20-31 in view of the following remarks is respectfully requested.

The Rejection of Claims 20, 24, and 27 Under 35 U.S.C. §102(b) as Being Unpatentable over Hormaza, *Sci Horti 79*:121-126, 1990.

Claims 20, 24, and 27 stand rejected under 35 U.S.C. §102(b) as being unpatentable over Hormaza, *Sci Horti 79*:121-126, 1990. The Examiner has taken the view that Hormaza teaches a method of cherry breeding comprising pollinating female flowers with a mixture of pollen from three parents, determining the phenotype of the progeny using molecular markers, determining the paternity of the progeny using RAPDS, and incorporating the selected progeny into a breeding program (citing pages 121-123, and pages 125-126).

It is respectfully submitted that Hormaza does not anticipate the claimed invention because the reference does not teach or suggest all the elements of Claim 20. In particular, Hormaza fails to teach or suggest step (c) evaluating progeny trees grown from each of the progeny lots using objective criteria to obtain a phenotype score, or step (e) using the pedigree and phenotype score to identify a plurality of elite trees having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of tree breeding to produce an advanced generation of conifer trees having increased genetic gain.

To anticipate, a reference must teach all of the elements of the claimed invention. If even one element of a claim is missing from the reference, the reference does not anticipate. As shown above, Hormaza lacks all of the steps of Claim 20, and thus does not anticipate this claim, nor Claims 24 and 27 which depend therefrom.

Moreover, Hormaza does not remotely suggest the claimed invention. Hormaza describes molecular marker-mediated selection in plant breeding, otherwise known as quantitative trait linkage (QTL) analysis. In particular, Hormaza describes *in vitro* embryo culture and RAPD marker-assisted selection of *in vitro* embryo cultures for agronomically interesting traits, to allow for "early discarding of non-interesting material at an early stage of the breeding program." See page 125. As described in Hormaza, "[s]ince the number of molecular markers linked to agronomically interesting traits in fruit and nut tree species is increasing rapidly (Mehlenbacher, 1995), screening for several traits of interest can be simultaneously achieved with the use of different markers." As further described at page 126, "[t]he use of molecular markers at a very early developmental stage allows a reduction in the number of seedlings grown to maturity since only the seedlings with the desired traits will be transferred to pots and/or the field."

In contrast to the method of Hormaza, the present invention does not rely on linking DNA markers with one or more phenotypic traits. Rather, the present invention is directed to the use of molecular analysis to determine the pedigree of progeny trees in conjunction with the *evaluation of progeny trees* grown from progeny lots using *objective criteria to obtain a phenotypic score*. As described in the specification, the term "objective criteria" refers to "the measurement of any plant characteristic or phenotype with any detection/measurement device that provides statistically meaningful data regarding the characteristic or phenotype being measured." Specification at page 10, lines 23-26. The term "phenotype score" is described in the specification as "the objective measurement of any phenotypic trait or characteristic that is desirable in a plant breeding program. Examples of desired phenotypic traits or characteristics include disease resistance, growth rate, growth habit, chemical composition of plant tissue, drought resistance, temperature hardiness, elevation adaptation, fecundity and so on."

Specification at page 10, lines 27-32. Applicants also wish to point out that the Board of Patent Appeals and Interferences previously acknowledged that the present invention is distinguished from methods using quantitative trait loci (QTL) associated with a desired trait. B.P.A.I. Decision on Appeal, Appeal No. 2006-0138, dated June 6, 2006, pages 8-9.

Therefore, as shown above, Hormaza lacks all of the steps of Claim 20, and thus does not anticipate or render obvious this claim, nor Claims 24 and 27, which depend therefrom. Accordingly, the Examiner is respectfully requested to remove this reference as a basis for rejection of Claims 20, 24, and 27 under 35 U.S.C. § 102(b).

The Rejection of Claims 20-29 Under 35 U.S.C. § 103(a) as Being Unpatentable Over Bridgwater, "Handbook of Quantitative Forest Genetics," L. Fins et al. (eds.), 1992, pp. 69-95, in View of Hormaza.

Claims 20-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bridgwater in view of Hormaza. The Examiner has taken the position that Bridgwater teaches the advantages of polymix-mediated tree breeding regarding selection for particular phenotypes such as resistance to rust disease, general combining ability, and gains in additive genetic variation. See Examiner's Answer, pages 20-21, mailed September 9, 2005. The Examiner has acknowledged that Bridgwater does not teach or suggest step (d) determining the pedigree of a plurality of progeny trees using DNA analysis. The Examiner has taken the view that Hormaza teaches the advantages of using DNA analysis to determine pedigree in a cherry breeding program. The Examiner then concludes that it would have been obvious to utilize the method of polymix breeding of Bridgwater and to modify the method by utilizing DNA analysis of pedigree of Hormaza. Applicants disagree with the Examiner's conclusions for the following reasons.

It is submitted that the Examiner has failed to establish a *prima facie* case of obviousness because there is no suggestion or motivation to combine the references, and even if the

references were to be combined, the combination fails to teach or suggest every limitation of the claimed invention.

As an initial matter, applicants disagree with the Examiner's characterization of Bridgwater as teaching the advantages of polymix-mediated tree breeding. Rather, applicants submit that Bridgwater teaches away from the use of polymix breeding by stating that "[i]f there is strong variation for general combining ability among males and inbreeding depression is present, selection in base populations produced from polycross matings will reduce expected gains since most selections may be progenies of the same few pollen parents." Bridgwater, page 75, first full paragraph. Therefore, the teachings of Bridgwater would not provide one with an expectation of success for one to use polymix breeding to produce an advanced generation having increased genetic gain, as claimed.

As described above, in connection with the rejection of Claims 20, 24, and 27 under 35 U.S.C. §102(b), Hormaza is generally directed to methods of molecular marker-mediated selection in plant breeding, otherwise known as quantitative trait linkage (QTL) analysis, and does not teach, suggest, or provide motivation to modify the teachings of Bridgwater to arrive at the claimed invention. In fact, Hormaza actually teaches away from the present invention by describing the use of marker-aided selection of *in vitro* cultures to avoid "the problems of the long juvenile period, the long generation times and the large plant size." Hormaza at page 122. Therefore, applicants submit that the Hormaza reference would not provide the required reasonable expectation of success for modifying the method of polymix breeding taught by Bridgwater to include the step of pedigree analysis of progeny.

Moreover, even if the teachings of Bridgwater and Hormaza were to be improperly combined, all the claim limitations would not be met. As acknowledged by the Examiner, Bridgwater does not teach or suggest step (d) determining the pedigree of a plurality of progeny

trees using DNA analysis. Applicants wish to point out that Bridgwater also fails to teach or suggest step (e) using the pedigree and phenotype score to identify a plurality of elite trees having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of tree breeding to produce an advanced generation of trees having increased genetic gain.

The teachings of Hormaza fail to cure the deficiencies of Bridgwater. As described above in connection with the rejection of Claim 20 under 35 U.S.C. § 102(b), applicants submit that Hormaza does not teach or suggest step (c) evaluating progeny trees grown from each of the progeny lots using objective criteria to obtain a phenotype score, or step (e) using the pedigree and phenotype score to identify a plurality of elite trees having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of tree breeding to produce an advanced generation of conifer trees having increased genetic gain.

Therefore, in view of the above, it is demonstrated that the combination of Bridgwater and Hormaza do not render the invention of Claim 20 obvious, nor Claims 21-29 which depend from Claim 20. Accordingly, the Examiner is respectfully requested to withdraw this combination of references as a ground of rejection of Claims 20-29 under 35 U.S.C. § 103(a).

The Rejection of Claims 20-31 Under 35 U.S.C. § 103(a) as Being Unpatentable Over Bridgwater, "Handbook of Quantitative Forest Genetics," L. Fins et al. (eds.), 1992, pp. 69-95, in View of El-Kassaby et al., *Theor. Appl. Genet. 83*(6-7):752-758, 1992, and Further in View of Stoehr et al., *Can. J. For. Res. 28*:187-195, 1998.

Claims 20-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bridgwater in "Handbook of Quantitative Forest Genetics," L. Fins et al. (eds.), 1992, pp. 69-95, in view of El-Kassaby et al., *Theor. Appl. Genet. 83*(6-7):752-758, 1992, and further in view of Stoehr et al., *Can. J. For. Res. 28*:187-95, 1998.

The Examiner has taken the view that Bridgwater teaches the use of polymix breeding and discusses tree breeding for genetic gain. The Examiner acknowledges that Bridgwater does not teach using DNA analysis to determine pedigree. The Examiner characterizes El-Kassaby et al. as teaching the use of molecular markers such as isozymes to determine the pedigree of progeny from a polymix cross. Stoehr et al. is cited by the Examiner as teaching the use of DNA markers to identify pedigree. The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to utilize the method of polymix tree breeding taught by Bridgwater, and to modify that method by utilizing the pedigree analysis step in the Douglas fir polymix breeding program taught by El-Kassaby et al., and to further modify that method by utilizing DNA markers as taught by Stoehr et al.

For the reasons set forth in detail below, applicants respectfully submit that the burden of establishing a *prima facie* case of obviousness has not been met because: (1) there is no suggestion to combine or modify the references' teachings; and (2) even if the references were to be combined, the combined teachings of the references fail to disclose every limitation of the claimed invention. As stated in the M.P.E.P. § 2143.03, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." Citing *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that Bridgwater does not teach or suggest step (d) determining the pedigree of a plurality of progeny trees using DNA analysis, or step (e) using the *pedigree and phenotype score to identify a plurality of elite trees* having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of

tree breeding to produce an advanced generation of conifer trees having increased genetic gain, as required by Claim 20.

As described above, Bridgwater merely provides a review of different types of mating designs used in breeding programs, including polymix breeding. The teachings of El-Kassaby et al. and Stoehr et al. fail to cure the deficiencies of Bridgwater. El-Kassaby et al. does not teach or suggest step (c) evaluating progeny trees grown from each of the progeny lots using objective criteria to obtain a phenotypic score, step (d) determining the pedigree of a plurality of progeny trees using DNA analysis, or step (e) using the *pedigree and phenotype score to identify a plurality of elite trees* having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of tree breeding to produce an advanced generation of conifer trees having increased genetic gain, as required by Claim 20. Rather, El-Kassaby et al. is directed to the use of protein markers to determine the paternity of progeny, and does not teach or suggest the use of DNA analysis, or DNA analysis in combination with a phenotypic score to identify a plurality of elite trees for inclusion in a breeding group.

In fact, El-Kassaby et al. actually teaches away from the invention for the following reasons. El-Kassaby et al. describes a study using a polymix of three-pollen donors chosen based on multilocus allozyme genotypes giving unambiguous determination of paternity to study male reproductive success. The three males in the study showed wide variation in reproductive success, leading to the conclusion, in concurrence with Bridgwater, that a drawback of the polymix breeding method is lack of male pedigree control. The solution proposed by El-Kassaby et al. teaches away from the invention by suggesting the use of a polycross with a few or single males to determine general combining ability. The reference notes "due to the increased co-ancestry among offspring, using fewer males prevents concurrent testing and selecting." El-Kassaby et al. at page 758. This teaching would not lead one to an expectation of

success for the use of a breeding program with concurrent pedigree testing as claimed. Therefore, applicants submit that the El-Kassaby et al. reference would not provide the required reasonable expectation of success for modifying the method of polymix breeding to include the step of concurrent pedigree analysis of progeny, nor does it teach the use of DNA analysis.

The teachings of Stoehr et al. do not cure the deficiencies of Bridgwater and El-Kassaby et al. The Examiner cites Stoehr et al. as teaching the use of DNA markers to identify pedigree in Douglas fir. However, Stoehr et al. does not teach or suggest using a pedigree and a phenotypic score to identify elite trees for use in a next generation of breeding, as required in steps (c) and (e) of Claim 20. Rather, Stoehr et al. use a polymeric genome marker to estimate the level of outside-orchard pollen contamination, supplemental mass pollination efficacies, and natural selfing in Douglas fir.

It is submitted that there is no expectation of success for combining the teachings of these references to result in the claimed invention for at least the reasons described above. Moreover, even if these referenced teachings were to be combined, the combined teachings fail to disclose all the limitations of the claimed invention, because none of the cited references teach or suggest step (e) of Claim 20 which recites using the *pedigree and phenotype score to identify a plurality of elite trees having an acceptable level of relatedness for inclusion in a breeding group for use in a next generation of tree breeding to produce an advanced generation of conifer trees having increased genetic gain*. Therefore, in view of the above, it is demonstrated that the combination of Bridgwater, El-Kassaby et al., and Stoehr et al. does not render the invention of Claim 20 obvious, nor Claims 21-29, which depend from Claim 20.

Claims 20-31 are believed to be allowable over the cited references for at least the reasons described above. As further evidence of the patentability of the claimed invention, applicants previously submitted evidence of secondary considerations in the response mailed on

August 4, 2006, demonstrating that there was a failure of others to provide a feasible solution to the long-standing problem of tree breeding, that the need was satisfied by the present invention, and evidence of copying of the present invention by others in the field. It is submitted that the evidence of secondary considerations, when properly view as a whole, supports the non-obviousness of the invention.

As stated in M.P.E.P. Section 716.01(d) "[W]hen an applicant timely submits evidence traversing a rejection, the examiner *must reconsider* the patentability of the claimed invention. The ultimate determination of patentability *must* be based on consideration of the *entire record*, by a preponderance of evidence, with *due consideration to the persuasiveness of any arguments and any secondary evidence.*" *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). "All of the competent rebuttal evidence taken as a whole should be weighed against the evidence supporting the *prima facie* case." *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984) (reversing the decision of the Board and concluding that the claimed subject matter would not have been obvious to one of ordinary skill at the time the invention was made). As stated in *In re Piasecki*:

> When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with facts on which the earlier conclusion was reached, not against the conclusion itself. *In re Piasecki*, 745 F.2d at 1472.

As further stated in M.P.E.P. 2144.08 IIB, "[c]onsideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments. Office personnel should avoid giving evidence no weight, except in rare circumstances . . . Office personnel should not evaluate rebuttal evidence for its "knockdown" value against the *prima*

facie case, *Piasecki,* 745 F.2d at 1473, 223 U.S.P.Q. at 788, or summarily dismiss it as not compelling or insufficient."

The Examiner has taken the view that the mathematical simulation of Purvis et al. is not probative, since no actual results were obtained. In support of the Examiner's position, the Examiner relies on Shelbourne at page 33 (Shelbourne, C.J.A., "Tree Breeding Methods," Technical Paper No. 55, New Zealand Forest Service, 1969) which states "numerical comparisons of predicted gains are of limited value, and are superseded by the practical realities and problems of a particular situation." Applicants disagree with the Examiner's characterization of Shelbourne in this regard. Applicants wish to point out that the portion of Shelbourne quoted by the Examiner does not state that numerical comparisons of predicted gains have no value. Rather, in the very next sentence, Shelbourne clarifies that in addition to numerical comparisons, "other important factors are the length of the period before the improved stock is available, the relative costs of different methods and stages of each method and the practical realities and problems of a particular situation." See Shelbourne, page 33.

In fact, contrary to the Examiner's assertion, the whole focus of the Shelbourne reference describes the value and importance of using mathematical comparisons of different breeding/testing/selection systems due to the long time required for actual field testing. See, *e.g.*, Shelbourne at pages 18-26. For example, Shelbourne states "[i]t is possible, provided estimates of certain population parameters are available, to make comparisons of predicted genetic gains from different breeding methods in quantitative genetic terms." Page 18, first paragraph. Shelbourne also supports the view that quantitative genetic theory holds up well in the real world. For example, as stated in Shelbourne, "[i]t is possible to compare predicted genetic gains for any species from the different breeding methods discussed previously provided heritabilities (broad and narrow sense) have been estimated for the trait under comparison." Page 27, first

paragraph. Therefore, it is submitted that the results of the Purvis et al. study support the patentability of the claimed invention.

The Examiner has asserted that the Burdon et al., De Castro et al., Wheeler et al., and Grattapaglia et al. references highlight the potential pitfalls of applicants' claimed method rather than demonstrating that it fulfills a long-felt need. Applicants disagree with the Examiner's assertion and characterization of these references in this regard.

As an initial matter, applicants wish to point out that the Board of Patent Appeals and Interferences previously considered the issues of written description and enablement and reversed the rejections based on lack of adequate written description and nonenablement. B.P.A.I. Decision on Appeal, Appeal No. 2006-0138, dated June 6, 2006, pages 6-9.

The Examiner has taken the view that DeCastro et al. (2004), Wheeler et al. (2006), and Grattapaglia et al. (2004) teach that equality of pollen fitness is a necessary requirement for applicants' claimed method of polymix breeding. Applicants strongly disagree, and wish to point out that the Board of Patent Appeals and Interferences previously considered this very issue and determined that the *assumption of equal reproductive success has no relevance to the claimed method* because the method involves a step of determining, via DNA analysis, the paternity of the selected elite progeny prior to using them in the next round of breeding (see pages 7-8 of B.P.A.I. decision mailed June 6, 2006).

Applicants also strongly disagree with the Examiner's assertion that "Grattapaglia et al. (2004) provide more evidence of unequal reproductive fitness in Eucalyptus, and also teach that Applicant admitted that insufficient markers existed to accurately determine pedigree in their breeding program." To the contrary, Grattapaglia et al. concludes that despite the fact that there was unequal reproductive success, the selection method was successfully applied, resulting in an average realized gain of 24.3% in volume growth of trees. See *e.g.*, Abstract, page 198.

Applicants also disagree with the Examiner's assertion that "Applicant admitted that insufficient markers existed to accurately determine pedigree in their breeding program." The passage in Grattapaglia et al. referenced by the Examiner merely states that the *total number* of chloroplast loci and nuclear microsatellite loci analyzed in the Lambeth 2001 study would need to be increased to obtain unambiguous paternal determinations. Moreover, the B.P.A.I. previously stated "since the evidence of record shows that those skilled in the art were familiar with the use of DNA markers to determine paternity in tree breeding research, we agree with the Appellants that those skilled in the art would not have considered a description of specific DNA markers to be necessary in order to show possession of the claimed method." B.P.A.I. Decision mailed June 6, 2006.

Applicants maintain that the above mentioned references demonstrate that the invention fulfills a long-felt need. For example, Wheeler et al. summarizes the state of the art prior to the invention as follows: "[t]he conventional way to drive modifications in old forest tree seed orchards is to establish progeny trials involving each parent tree and then evaluate its contribution to the performance of the progeny by estimating its general and specific combining ability (GCA and SCA). In this work, we successfully applied an alternative parent selection tactic . . . ." (Wheeler, Abstract, 1st Col.). The Wheeler et al. reference then describes the practice of the method of the present invention and goes on to state "[a]n average realized gain of 24.3% in volume growth was obtained from the selection of parents as measured in forest stands at age 2-4 years." (Abstract, 2nd Col.).

Therefore, in view of the above, it is demonstrated that the combination of Bridgwater, El-Kassaby et al. and Stoehr et al. does not render Claims 20-31 obvious. Accordingly, the Examiner is respectfully requested to withdraw this combination of references as a ground for rejection of Claims 20-31 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing remarks, applicants submit that all of the pending claims are in condition for allowance and notification to this effect is respectfully requested.

Respectfully submitted,

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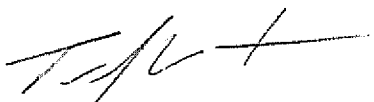

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